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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---------------------------------|------------------------------|------------------|
| 10/614,923 | 07/08/2003 | Marie-Claire Grosjean-Courmoyer | A34658-PCT-USA-1 (072667) | 3094 |
| 21003 | 7590 | 04/07/2006 | EXAMINER | |
| BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 | | | SCHLAPKOHL, WALTER | |
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1636

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|---|------------|
| Office Action Summary | Application No. 10/614,923 | Applicant(s) GROSJEAN-COURNOYER ET AL. | |
| | Examiner Walter Schlapkohl | Art Unit 1636 | <i>WLF</i> |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/937,236.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/18/05 & 10/10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of the papers filed 1/17/2006 in which claim 14 was canceled and claims 20-35 were added.

Specification

Receipt is acknowledged of the correction to the specification which now reflects the updated status of US Patent Application 09/937,236 as US Patent 6,617,163. The objection to the specification is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 30, and therefore dependent claims 21-29 and 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

This is a new rejection necessitated by Applicant's amendment.

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Claim 20 recites "[a] method for identifying a gene associated with a detectable phenotype in a fungus, comprising: (a) transforming the fungus with a polynucleotide comprising a marker gene which would otherwise be transcriptionally active in the fungus but which has been inactivated by the insertion of an *Impala* transposon, said marker gene comprising, in the direction of transcription, a promoter regulatory sequence of the *niaD* gene from *Aspergillus nidulans* which is more than 0.4 kb long, under conditions which allow the excision of the *Impala* transposon from said marker gene and its reinsertion into the genome fungus" in lines 1-8. Claim 20 is vague and indefinite in that it appears at least one other component of the marker gene has been omitted; otherwise, it is unclear what Applicant intends "in the direction of transcription" to indicate. Did Applicant intend to include a coding sequence or some other component downstream of the recited promoter, or does the phrase "in the direction of transcription" intend to confer some sort of structural limitation to the recited promoter?

Claim 20 is also vague and indefinite in that it is unclear which conditions allow for the excision of the *Impala* transposon and its reinsertion into the genome of the fungus, especially in such cases wherein the *Impala* transposon is defective.

(Applicant has specifically noted in the specification that

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"*Impala* transposon" encompasses "modified *Impala* transposons" (page 12, lines 19-20) which includes defective *Impala* transposons.) Does Applicant intend conditions in which a transposase capable of excising the transposon is simultaneously expressed in the fungus or are there other conditions which must be met?

Similarly, claim 30 recites "[a] method for identifying a gene associated with a detectable phenotype in a fungus, comprising: (a) transforming the fungus with a polynucleotide comprising a marker gene which would otherwise be transcriptionally active in the fungus but which has been inactivated by the insertion of a non-mobile *Impala* transposon, said marker gene comprising, in the direction of transcription, a promoter regulatory sequence of the *niaD* gene from *Aspergillus nidulans* which is more than 0.4 kb long, under conditions which allow the excision of the *Impala* transposon from said marker gene and its reinsertion into the genome fungus" in lines 1-7. Claim 30 is vague and indefinite in that it appears at least one other component of the marker gene has been omitted; otherwise, it is unclear what Applicant intends "in the direction of transcription" to indicate. Did Applicant intend to include a coding sequence or some other component downstream of the recited promoter, or does the phrase "in the direction of

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transcription" intend to confer some sort of structural limitation to the recited promoter?

Claim 30 further recites "(b) mobilizing the non-mobile *Impala* transposon using a transposase, the expression of which is controlled, under conditions which allow the excision of the defective *Impala* transposon, its reinsertion and its stabilization in the genome of the fungus" in lines 8-10. Claim 30 is also vague and indefinite in that it is unclear whether Applicant considers a "defective" *Impala* transposon to be the same as a "non-mobile" *Impala* transposon. Either way, "the defective *Impala* transposon" lacks clear and positive antecedent basis. However, claim 30 is also vague and indefinite in that it is unclear how a "non-mobile *Impala* transposon" can be "mobilized," i.e., is the transposon converted into a "mobile" transposon before mobilization and under which conditions could the movement of a non-mobile transposon transpire?

Claim 30 is also vague and indefinite in that it is unclear which conditions allow for the excision of the *Impala* transposon, its reinsertion and its stabilization in the genome of the fungus, especially in such cases wherein the *Impala* transposon is defective. Does Applicant intend conditions in which a transposase capable of excising the transposon is simultaneously expressed in the fungus and in which the

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transposon has retained certain structural features, or are there other conditions which must be met?

Claims 27, 30 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection necessitated by Applicant's amendment.**

The specification as originally filed does not provide support for the invention as now claimed: a method for identifying a gene associated with a detectable phenotype in a fungus comprising transforming the fungus with a polynucleotide comprising a marker gene "wherein the marker gene encodes a nitrilase" (claims 27 and 32). Neither does the specification provide for a "non-mobile *Impala* transposon" (claim 30). The specification does not provide sufficient blazemarks nor direction for the instant marker genes and non-mobile transposons encompassed by the above-mentioned limitations, as currently recited. The instant claims now recite limitations, which were not clearly disclosed in the specification as filed,

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and now change the scope of the instant disclosure as filed.

Such a limitation recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of

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such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

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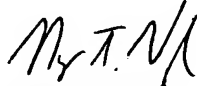
For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

March 31, 2006


NANCY VOGEL
PRIMARY EXAMINER